



Figure 1. Kaplan-Meier Curve of Freedom from All Cause Mortality.

At 30 days, 6 months, one year, 2 years and 3 years 96.8%, 94.2%, 93.1%, 90.5% and 86.4 of patients were free from all-cause mortality, respectively.

## CRT-137

### Clinical Outcome In Patients With Low Left Ventricular Function Undergoing Transcatheter Aortic Valve Replacement

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**Background:** Left ventricular ejection function (LVEF) recovers in the majority of patients with aortic stenosis (AS) who undergo aortic valve replacement. However the outcomes of patients with low EF who undergo transcatheter aortic valve replacement (TAVR) are not well defined.

**Methods:** Retrospective analysis of AS patients with normal versus mildly or severely impaired left ventricular function who underwent TAVR was done. Patients were divided according to baseline LVEF as normal ( $LVEF \geq 0.50$ ), mild-moderate ( $0.40 \leq EF < 0.50$ ) and severe ( $LVEF < 0.40$ ) dysfunction.

**Results:** A total of 242 patients were included in the present analysis. 163 patients (67%) had normal LVEF, 43 had mild-moderate (18%) and 36 (15%) had severe LV dysfunction. Baseline demographics were generally comparable apart from higher rates of women and STS score among patients with LV dysfunction (Table). There was no difference in access approach with 72% of the patient having transfemoral access. No significant difference in the in hospital and long term outcome were found (Table).

**Conclusions:** Patients with severe AS and impaired LV function who undergo TAVR may gain similar benefit from the procedure as patients with normal LV function.

Table

	Normal n=163	Mild-mod n=43	Severe n=36	p value
<b>Demographics</b>				
Age $\pm$ SD	84 $\pm$ 7	84 $\pm$ 7	85 $\pm$ 7	0.87
Male	42%	63%	61%	0.01
STS score	10.5 $\pm$ 3.8	10.2 $\pm$ 3.2	12.6 $\pm$ 5	0.03
HTN	92%	94%	97%	0.84
Diabetes	30%	22%	38%	0.39
Renal failure	54%	55%	70%	0.28
Hx of MI	11%	19%	29%	0.07
Hx of CABG	32%	47%	41%	0.23
<b>Procedural outcome</b>				
Major vascular complication	10.3%	19.4%	3.8%	0.18
Stroke	4.7%	10.5%	12.1%	0.15
Major bleed	12.7%	7.4%	7.4%	0.81
In hospital mortality	6%	2.6%	3%	0.72
1-year mortality	20%	14%	19%	0.65

## CRT-138

### Initial US Experience with Commercial Transfemoral Sapien Transcatheter Heart valve compared to PARTNER Cohort B

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**Background:** Edwards Sapien transcatheter valve is FDA approved for commercial use in non-operable patients with severe symptomatic aortic stenosis (AS) via the transfemoral approach.

**Objective:** To assess the clinical profile and in-hospital complications in patients treated with commercial valve compared to PARTNER cohort B.

**Methods:** Study included all consecutive patients treated with commercial Sapien valve at our institution. Baseline characteristics, clinical presentation and in-hospital complications were analyzed. Among all transfemoral cases 37 commercial valve patients were compared to 54 patients in cohort B.

**Results:** All clinical variables are similar between the groups including STS score ( $9.4 \pm 4$  vs.  $10.7 \pm 5$ ,  $p=0.24$ ) except commercial patients had more insulin dependent diabetes mellitus and dialysis dependent renal failure. In majority of the patients in the commercial arm the procedure was done with conscious sedation (81% vs. 56%,  $p=0.02$ ). The use of planned surgical cut down for vascular access is also rare (4% vs. 85%,  $P<0.001$ ) in commercial group. 100% procedural success in both the groups with valve deployment. There is trend for lower vascular and bleeding complications with less blood transfusion rates (27% vs. 59%,  $p=0.007$ ) in the commercial patients. The in-hospital mortality and stroke rates are similar between the groups.

**Conclusions:** The initial commercial use of the Edwards Sapien valve for inoperable patients reported to have similar success rates in valve deployment, in-hospital mortality and stroke rate when compared to PARTNER cohort B patients. The refinement in the procedure with more conscious sedation, experience of the operators and careful vascular planning with more percutaneous access in the commercial group lead to the trends for lower vascular complications and the requirement of blood transfusions.

## Clinical and procedural characteristics and in-hospital complications

Variable	Commercial Valve (n=37)	Cohort B (n=54)	p value
Mean age (years±SD)	83±8	83±7	0.87
Dialysis	11%	0	0.04
Conscious sedation	81%	56%	0.02
Planned surgical cut down	4%	85%	<0.001
VARC major vascular complication	5%	22%	0.14
VARC life threatening bleed	9%	13%	0.69
Transfusion rates	27%	59%	0.007
Stroke	8%	11%	1
In-hospital mortality	2	0	0.1

## Closure of Valve Leaks

## CRT-139

## A Single Center Experience Of Percutaneous Transcatheter Closures Of Paravalvular Leaks

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**Background:** Percutaneous transcatheter closure of Paravalvular leaks is a new alternative approach to re-do surgery, which is associated with considerable mortality and morbidity. We aim to evaluate feasibility and short term results with this novel closure technique.

**Methods:** Between May 2007 and September 2011. 16 symptomatic patients (seven males, nine females; mean age  $59.1 \pm 17.9$  years) with heart failure (n=9), hemolytic anemia (n=2) or both (n=5) underwent percutaneous PVL closure at our center. Most patients were high risk for open surgical repair (STS score  $7.64 \pm 8.02$ ) with average number of sternotomies equal to 2.3 (range 0-4). Both left and right sided valves were intervened upon including Mitral valves (n=10), Aortic valves (n=5), one of which was a trans-catheter placed Sapien Valve, Pulmonic valves (n=1). The procedure was done under echocardiographic and fluoroscopic guidance using the Amplatzer Septal Occluder, Duct Occluder or Vascular Plug II.

**Results:** Successful percutaneous repair was achieved in 12 out of 16 patients (75%). Failure to cross the leak with either the wire or the catheter occurred in two patients. In the other two patients, device was deployed with residual moderate regurgitation. There were no procedural or unexplained death, but there were two post procedural deaths, one patient had severe septic shock and the other had cardiogenic shock prior to intervention. No emergency surgery or device embolization occurred. One patient had an ischemic stroke in the fifth post-operative day. One patient with multiple defects and a failed attempt required an elective surgical repair to seal the leak.

**Conclusions:** Percutaneous transcatheter closure of paravalvular leaks is feasible but appears to be technically demanding procedure with acceptable success rate especially in poor surgical candidate. Further experience is warranted to evaluate long term morbidity and mortality.

## CRT-140

## Percutaneous Mitral Valve Repair with MitraClip Restores Exercise Capacity in Patients with Symptomatic Severe Functional Mitral Regurgitation who are Not Surgical Candidates

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**Introduction:** Functional Mitral Regurgitation (FMR) may cause Heart Failure (HF). Cardiac surgery for open correction of FMR in patients with severely impaired left ventricular ejection fraction (LVEF) or prior cardiac surgery entails higher risk. The EVEREST II Trial in patients who were surgical candidates for mitral valve repair showed outcomes of percutaneous repair using the MitraClip were comparable with surgery.

**Hypothesis:** We hypothesized that MitraClip is safe and effective in patients with severe FMR and HF who are not surgical candidates.

**Methods:** We identified 4 patients with significant FMR and limited exercise capacity due to HF. Significant ischemia was excluded with functional imaging. Surgical risk was deemed prohibitive. Mitral valve anatomy was assessed by transthoracic (TTE) and transesophageal echocardiography.

**Patients:** One patient was female, 2 had AF, 3 had prior remote coronary artery bypass graft surgery, and the 4th had non-ischemic cardiomyopathy. Age was  $59 \pm 11$  years, BSA  $1.7 \pm 0.1$  m<sup>2</sup>, GFR  $57.5 \pm 46.9$  ml/min, Hemoglobin  $11.2 \pm 1.4$  g/dL. NYHA  $2.75 \pm 0.5$ , LVEF  $30 \pm 17\%$ , MR grade  $3.75 \pm 0.5$ , Six-Minute Walk Distance (6MWD)  $208 \pm 132$  m, and Euroscore risk for cardiac surgery  $32.9 \pm 26.9\%$ .

**Results:** All patients underwent successful MitraClip procedures without complication. Three patients used 1 clip, while 1 patient required 2 clips. MR grade was reduced to  $1.25 \pm 0.5$  and patients were discharged  $2.25 \pm 0.96$  days post MitraClip. Follow-up TTEs show durability of MR reduction (Fig 1). 6MWD improved to  $423 \pm 92$  m (p=0.037). Two patients have resumed working, and all can participate in normal activities of daily living. They remain on standard pharmacotherapy for heart failure.

**Conclusion:** In conclusion, MitraClip is safe and effective in restoring exercise capacity in selected patients with severe FMR and HF who are not surgical candidates.

